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510(k) Summary for the
Dimension Vista™ System Drugs of Abuse Positive Control
(UDAT CONT (+) – KC515)
and
Dimension Vista™ System Drugs of Abuse Negative Control
(UDAT CONT (-) – KC516)

A. 510(k) Number: K062191

B. Analytes: Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC).

C. Type of Test: Drugs of Abuse Controls

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ System Drugs of Abuse Positive Control
(UDAT CON (+) – KC515)
Dimension Vista™ System Drugs of Abuse Negative Control
(UDAT CON (-) – KC516)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862 - 3280 – Clinical toxicology control material
2. Classification: Class I
3. Product Code: DIF – Drug Mixture Control Material
4. Panel: Toxicology

G. Intended Use: The Dimension Vista™ System Drugs of Abuse Positive Control is an *in vitro* diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension Vista™ System.

The Dimension Vista™ System Drugs of Abuse Negative Control is an *in vitro* diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension Vista™ System.

H. Device Description:

The Dimension Vista™ System Drugs of Abuse Positive Control is a liquid, multi-analyte, human urine-based product containing the following constituents at above the cutoff levels of the methods:

Analyte	Constituent
Amphetamine/Methamphetamine	D-methamphetamine
Barbiturate	Secobarbital
Benzodiazepines	Nordiazepam
Cocaine Metabolite	Benzoylecgonine
Methadone	Methadone
Opiates	Morphine
Phencyclidine	Phencyclidine
Cannabinoids	11-nor-Δ^9-THC-9 –COOH

The kit consists of six vials which are ready for use (no preparation is required). The volume per vial is 2.5 mL.

The Dimension Vista™ System Drugs of Abuse Negative Control is a liquid, multi-analyte, human urine-based product containing the following constituents below the cutoff levels of the methods:

Analyte	Constituent
Amphetamine/Methamphetamine	D-methamphetamine
Barbiturate	Secobarbital
Benzodiazepines	Nordiazepam
Cocaine Metabolite	Benzoylecgonine
Methadone	Methadone
Opiates	Morphine
Phencyclidine	Phencyclidine
Cannabinoids	11-nor-Δ^9-THC-9 –COOH

The kit consists of six vials which are ready for use (no preparation is required). The volume per vial is 2.5 mL.

I. Substantial Equivalence Information:

The Dimension Vista™ System Drugs of Abuse Positive Control and the Dimension Vista™ System Drugs of Abuse Negative Control are substantially equivalent to the Dimension® Drugs of

Abuse Positive Control (DC43A) and the Dimension® Drugs of Abuse Negative Control (DC44A), both products cleared under K950138. The following table summarizes product similarities and differences:

	New Device	Predicate Device
Item	**Dimension Vista™ System Drugs of Abuse Positive Control**	**Dimension® Drugs of Abuse Positive Control (DC43A) K950138**
Intended Use	The Dimension Vista™ System Drugs of Abuse Control is an *in vitro* diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension Vista™ System.	The Drugs of Abuse Positive Control is an *in vitro* diagnostic product intended as quality control product for the following methods packaged in Flex® reagent cartridges: Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC).
Analytes	Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC).	Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC).
Form	Liquid.	Liquid.
Traceability	GC/MS[1].	GC/MS.
Matrix	Human urine based.	Human urine based.
Number of Levels	One Level.	One level.

[1] Gas Chromatography / Mass Spectrometry.

	New Device	Predicate Device
Item	**Dimension Vista™ System Drugs of Abuse Negative Control**	**Dimension® Drugs of Abuse Negative Control (DC44A) K950138**
Intended Use	The Dimension Vista™ System Drugs of Abuse Control is an *in vitro* diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension Vista™ System.	The Drugs of Abuse Positive Control is an *in vitro* diagnostic product intended as quality control product for the following methods packaged in Flex® reagent cartridges: Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC).
Analytes	Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and	Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and

	Cannabinoids (THC).	Cannabinoids (THC).
Form	Liquid.	Liquid.
Traceability	GC/MS[1].	GC/MS
Matrix	Human urine based.	Human urine based.
Number of Levels	One level.	One level.

[1] Gas Chromatography / Mass Spectrometry.

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004
Guidance for Industry – Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material
Guidance for Industry and FDA Staff – Bundling Multiple Devices or Multiple Indications in a Single Submission

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. Stability: Target shelf life for both the Dimension Vista™ System Drugs of Abuse Positive Control and the Dimension Vista™ System Drugs of Abuse Negative Control is twelve months. Control shelf life is determined by comparing results of the product stored at 4°C with control stored at -20°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined. Percent change is than or equal to 10%. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.
A vial punctured by the instrument and stored on board is stable for seven days.
An open vial not on instrument, but recapped and stored in a refrigerator is stable for 31 days.

For testing, vials are opened /punctured on day zero. For punctured vials, a quantity sufficient for multiple tests is removed and the vials are recapped, punctured and stored at 2-8°C. Punctured vials are tested on Day 8, 15, 22, and 32 vs. freshly opened vials.

2. Traceability: The assigned values of the Dimension Vista™ System Drugs of Abuse Positive Control and the Dimension Vista™ System Drugs of Abuse Negative Control are traceable to Gas Chromatography / Mass Spectrometry (GC/MS) Reference Testing.

3. Bottle Value Assignment:

Calculated quantities of D-Methamphetamine, Secobarbital, Nordiazepam, Benzoylecgonine, Methadone, Morphine, Phencyclidine, and 11-nor-Δ^9-THC-9-COOH high purity stock solutions are added to drug free normal human urine to target concentrations for each of the Negative and Positive Controls.

The Negative and Positive Bulk Products are tested by GC/MS[1]. Values are assigned to the controls once the GC/MS results are in the acceptable ranges.

[1] Gas Chromatography / Mass Spectrometry

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Victor M. Carrio
RA/QS Compliance Manager
Dade Behring, Inc.
Mailstop 514
500 GBC Drive
Newark, DE 19714-6101

AUG 2 1 2006

Re: k062191
Trade/Device Name: Dimension Vista™ System Drugs of Abuse Positive Control (UDAT CON (+) – KC515)
Dimension Vista™ System Drugs of Abuse Negative Control (UDAT CON (-) –KC516)
Regulation Number: 21 CFR §862.3280
Regulation Name: Clinical Toxicology Control Material
Regulatory Class: Class I
Product Code: DIF
Dated: July 27, 2006
Received: July 31, 2006

Dear: Mr. Carrio

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K062191

Device Name:

Dimension Vista™ System Drugs of Abuse Positive Control
(UDAT CON (+) – KC515)
Dimension Vista™ System Drugs of Abuse Negative Control
(UDAT CON (-) – KC516)

Indications for Use:

The Dimension Vista™ System Drugs of Abuse Positive Control is an *in vitro* diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension Vista™ System.

The Dimension Vista™ System Drugs of Abuse Negative Control is an *in vitro* diagnostic product intended as quality control product for the Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) methods on the Dimension Vista™ System.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062191